K042638

AURIDENT, INC.

P.O. Box 7200 • Fullerton, California 92834
(800) 422-7373 • (714) 523-5544
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DEC 17 2004

510(k) Summary:

Contact: Bruce D. Spivack

Date Prepared: September 22, 2004

Device Classification Name: Class II, Porcelain Powder for Clinical Use (872.6660), EIH

Trade Name: Radiance Porcelain

Predicate Devices: Willi Geller Creation Porcelain, k981490
Finesse Low Fusing Porcelain, k954761
Vita Omega Porcelain, k921474

Device Description: Radiance Porcelain system is a sodium/potassium alumina silicate based leucite glass ceramic, porcelain system for the fabrication of either porcelain fused to metal or all ceramic restorations. Radiance porcelain can only be used with its corresponding leucite glass ceramic pressable, Press-I-Dent for the fabrication of all ceramic systems and therefore constitute one complete porcelain system.

Intended Use: Radiance Porcelain is intended for the fabrication of dental restorations, crowns, bridges, veneers, inlays, and onlays, using either dental alloys or its pressable component, Press-I-Dent.

Technological Characteristics: All the components in the Radiance System have been used in legally marketed devices. This system has been on the European market since 1999 and enjoys full CE marking from the manufacturer. Because of the similarities between the Radiance System and the predicated devices, we felt that no further biocompatibility testing was necessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Mr. Bruce D. Spivack
Manager, Sales and New Product Development
Aurident, Incorporated
610 South College Boulevard
Fullerton, California 92831

Re: K042638
Trade/Device Name: Radiance Porcelain
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 6, 2004
Received: December 9, 2004

Dear Mr. Spivack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AURIDENT, INC.

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Indications for Use

510(k) Number (if known): K042638

Device Name: Radiance Porcelain

Indications For Use:

Radiance Porcelain is a sodium/potassium alumina silicate leucite glass ceramic porcelain system for the fabrication of dental restorations, crowns, bridges, veneers, inlays, and onlays, using either dental alloys or its pressable component, Press-I-Dent.

This porcelain system is a lower fusing porcelain than feldspar based porcelains and is manufactured from the fritting of manufactured glass compositions. In addition, it has lower opposing occlusal wear characteristics than feldspar based porcelains.

Radiance is intended for use by dental laboratories as an alternative to other porcelains.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number: K042638